

Long-term results of RTOG 0236 confirm good primary tumor control, positive five-year survival rates

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Patients with inoperable, early-stage lung cancer who receive stereotactic body radiation therapy (SBRT) have a five-year survival rate of 40 percent, according to research presented today at the American Society for Radiation Oncology's (ASTRO's) 56th Annual Meeting. Such a positive survival rate is encouraging considering that historically conventional RT resulted in poor tumor control for patients with inoperable lung cancer. This study is an update of RTOG 0236, originally published in 2010 , and also conducted by the original researchers to evaluate tumor control rates and side effects for patients at five years post-treatment.

RTOG 0236 was a Phase II North American multicenter trial from May 2004 until October 2006 of [patients](#) age 18 and older with biopsy-proven peripheral T1-T2 N0M0 non-small cell [lung cancer](#) (early stage with no lymph node involvement or metastases). Patients in the study all had medical conditions that precluded them from surgery, so they received SBRT, a specialized type of external beam therapy that uses focused radiation beams at a tumor using detailed imaging. SBRT delivers high doses of radiation to the tumor in a decreased amount of treatment time, compared to standard RT, while minimizing exposure to surrounding healthy organs. SBRT appeared to improve tumor control, as suggested by the initial study results for RTOG 0236.

A total of 59 patients were accrued for the study, and 55 were evaluable

(44 patients with T1 tumors and 11 patients with T2 tumors). Patients each received three fractions of 18 Gy (54 Gy total) of SBRT, and treatment lasted between one-and-a-half to two weeks.

Researchers evaluated local control, which is the rate of reoccurrence of the cancer at the site of origin, as well as disease-free survival, overall survival and toxicity (side effects). Median follow-up was four years (7.2 years for surviving patients). At five years, the rates for disease-free and overall survival were 26 percent and 40 percent, respectively, with a median overall survival of four years.

Only four patients had recurrences at the primary tumor site, resulting in an estimated five-year primary tumor failure rate of seven percent (range, 1.8 to 4.8 years after SBRT). Nine additional patients had recurrence within the involved lobe (range, 0.1 to 5.9 years after SBRT), resulting in a five-year primary tumor and involved lobe (local) failure rate of 20 percent.

The five-year local-regional failure rate was 38 percent, of which seven patients experienced a spread of the cancer to nearby lymph nodes or organs (range, 2.8 to 5.2 years after SBRT). Fifteen patients had disseminated recurrence (throughout the lung), thus the five-year disseminated failure rate was 31 percent. Treatment-related grade three and grade four side effects were reported in 15 patients and in two patients, respectively. No grade five adverse events were reported.

"Historically, when treating early lung cancer with radiotherapy, progression at the site of the [primary tumor](#) was the most common failure resulting in suffering and death," said lead study author Robert Timmerman, MD, professor and vice chair of the department of radiation oncology at the University of Texas Southwestern Medical Center in Dallas. "The initial results of RTOG 0236 showed very good tumor control; however, many physicians were concerned that treatment-

related toxicity would eventually appear, so SBRT has not seen widespread use. This long-term analysis confirms that treated tumors did not reappear at the original site; and late toxicity, beyond what was seen in the initial report, did not appear. However, metastatic tumors continued to appear over time in untreated sites likely because those tumors were so small at initial treatment that they were not detected. These five-year results demonstrate positive tumor control and disprove the misconception that short-course treatment will result in late-appearing, unacceptable toxicities."

More information: The abstract, "Long-term Results of RTOG 0236: A Phase II Trial of Stereotactic Body Radiation Therapy (SBRT) in the Treatment of Patients with Medically Inoperable Stage I Non-Small Cell Lung Cancer," will be presented in detail during a scientific session at ASTRO's 56th Annual Meeting at 10:45 a.m. Pacific time on Monday, September 15, 2014.

Provided by American Society for Radiation Oncology

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